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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,659	02/25/2002	Maurice Cohen	6171.US.D2	6272

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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/082,659

Applicant(s)

COHEN ET AL.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 December 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) 5-9 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Response to Amendment and Arguments

1. Claims 1-9 are pending.

Claims 5-9, drawn to non-elected inventions are withdrawn from examination.

Claims 1 and 4 have been amended.

Claims 1-4 are examined on the merits.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Specification

3. The disclosure is no longer objected to because the specification has been amended to rectify the informalities listed in the first action of merits (FAOM), mailed August 12, 2003.

Withdrawn Objection

Claim Objections

4. Claim 1 is no longer objected the non-elected subject matter, SEQ ID NO: 1-3 has been deleted from the claim.

Withdrawn Rejection

Claim Rejections - 35 USC § 112

5. The rejection of claims 1-4 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn.

6. The rejection of claims 1-4 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of the amendment to claim 1.

Maintained Rejections

Claim Rejections - 35 USC § 112

7. The rejection of claims 1-4 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention is maintained.

Applicants argue that the molecules designated, as PS190 are known to be connected to diseases involving the prostate, see Remarks, page 8, first full paragraph. Applicants point out passages within the specification describing the effectiveness of PS190 as a prostate tumor marker and conclude that SEQ ID NO: 4 and its fragments or complements would indicate the presence of prostate disease. The Examiner has

considered these arguments as well as reviewed those sections of the specification pointed out by Applicants and found these points of view unpersuasive.

Claims 1-4 are broadly drawn to a polynucleotide defined as SEQ ID NO: 4 and complements thereof, which encode at least one epitope. SEQ ID NO: 4, as well as complements thereof are to be used in methods of detecting a target polynucleotide or mRNA within a test sample (such as blood, urine, saliva and stool) in order to assess whether or not the test sample contains a polynucleotide indicative of prostate cancer, see page 57, lines 9-13; page 59, lines 30-34; and page 80, lines 1-10. These diagnostic methods include for example hybridization techniques, polymerase chain reaction, as well as reverse transcription polymerase chain reaction.

Applicants' specification has not evidenced enabling disclosure in which a definitive prostate cancer diagnosis can be made with any complement of SEQ ID NO: 4, nor the full-length sequence of SEQ ID NO: 4. The analysis set forth in the FAOM, paragraph 8 is still necessary. And while the Patent Office does not to produce any astonishing and results, they must bear some resemblance to what is considered essential to the invention. It is questionable that one of ordinary skill in the art would be able to arbitrarily select a complement of SEQ ID NO: 4 and implement this sequence in a method of diagnosis. The specification continues to be remiss of support enabling the skilled artisan to implement SEQ ID NO: 4 or undefined complements thereof in any form of cancer diagnosis. The specification does not enable one of ordinary skill in the art to definitively assess the incidence of any type of cancer, particularly prostate cancer in a test sample. There is no disclosure designating which complements or what criteria

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is used for discerning which nucleic acid residues would be effective in any diagnostic method. The experimental design presented in the specification lacks information regarding the applicability of SEQ ID NO: 4 and complements thereof in diagnostic methods relative to prostate diseases.

Based on the analysis set forth it would require undue experimentation for the skilled artisan to practice this invention because there is no support in the specification for the enablement of the broadly claimed invention. Therefore, in view of the insufficient guidance in the specification, extensive experimentation would be required to enable the claims.

Claim Rejections - 35 USC § 101

8. The rejection of claims 1-4 under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, credible or asserted utility or a well established utility is maintained.

Applicants have amended claims 1 and 4, as well as defined the term, epitope in attempts to obviate the pending rejection. Applicants also rely on the arguments presented in the traversal of the 35 USC § 112, first paragraph enablement rejection. These arguments and points of view have been carefully reviewed and considered, but found unpersuasive.

The applicability of Applicants' undefined complement of SEQ ID NO: 4 in methods of diagnosing prostate disorders and prostate cancer is not clear to one of ordinary skill in the art. Applicants' arguments suggest that one of ordinary skill in the art can use any arbitrary fragment of SEQ ID NO: 4 consisting of 312 amino acid

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residues in molecular based assays yielding a definitive prostate cancer diagnosis. And while Applicants assert that SEQ ID NO: 4 is effective in the suggested methodologies and even if that was found to be credible the implied utility of undefined and arbitrary fragments of SEQ ID NO: 4 surely would not. A polynucleotide encoding an arbitrary epitope may not encode a molecule useful for the implied utility of the claimed invention. The instant invention as claimed has no utility and is not enabling because one cannot, following the guidance presented in the specification that the claimed SEQ ID NO: 4 and its complements thereof without determining a property of an epitope would lend itself to a specific, substantial and credible use.

Claims 1-4 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial or credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The examiner can normally be reached on 7:00 am to 4:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne "Bonnie" Eyler, Ph.D. can be reached on (571) 272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

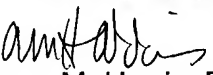
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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.
PRIMARY EXAMINER


Alana M. Harris, Ph.D.
02 March 2004